K100005

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 16 2010

1. **Submitted By:** April 7, 2010

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Manager, Regulatory Affairs

Becton, Dickinson and Company
BD Medical Diabetes Care
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Franklin Lakes, NJ 07417

Phone: 201-847-4298
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2. **Device Name:**

Trade Name:	BD 32G x 4mm Pen Needle
Common Names:	Pen Needle
Classification Name:	Hypodermic Single Lumen Needle
Classification:	Class II

3. **Predicate Device:**
BD Pen Needle 31G x 5mm
BD Pen Needle 31Gx 8mm
Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

BD pen needles are single use, sterile, medical devices designed to be use in conjunction with pen injectors and pen cartridges. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G and 31G) and lengths (5mm, 8mm and 12.7mm). BD Pen Needles are sterile (gamma irradiation sterilization), non-toxic and non-pyrogenic.

The pen needle assembly consists of a doubled-ended cannula that is assembled into an injection-molded hub using adhesive. The hub has internal threads, which allows it to be screwed onto the pen-injector device. This allows the Non Patient (NP) end of the cannula to penetrate through the rubber septum of the cartridge. The Patient end and NP end of the cannula are lubricated using a silicone based lube for ease of injection and rubber septum

penetration. An injection-molded inner shield is assembled over the Patient end of the Cannula to protect the point from damage and accidental needle-sticks. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away (tear drop) label to provide sterility barrier and tamper evidence. The Outer cover is also used to remove the hub and cannula from the pen. The peel-away label is pre-printed with information, which includes the lot number and needle gauge / length. The individual needle assemblies are packaged in bags and / or cartons, and placed into shippers with appropriate labeling. The shipper cases are palletized and sterilized.

The purpose of this 510(k) Premarket Notification is to expand the product offering to include a 32G x 4mm Pen Needle. The intended use for the modified device remains the same as the predicate device.

5. **Intended Use:**

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

6. **Technological Characteristics:**

The principal device of this premarket notification is the result of a design change to the predicate device (K051899) conducted in accordance with Quality System Regulations. The only change to the modified device is that the cannula gauge is smaller (32G) and the cannula length is shorter (4mm). The modified BD Pen Needle is equivalent to the predicate BD Pen Needle devices, given that the modified device:

- Has the same intended use and indications for use
- Provides equivalent glycemic control and similar safety profile
- Uses the same operating principles
- Incorporates the same basic design
- Has the same identical technological characteristics and perform equivalently.
- Is manufactured from the same materials
- Is sterilized using the same mode
- Is sterilized with SAL of 10-6
- Is packaged using similar unit, carton and case materials

The only difference between the Principle and Predicate BD Pen Needle device is the smaller size of the cannula.

7. **Substantial Equivalence:**

A clinical study was conducted on the BD 32G x 4mm Pen Needle. This study demonstrated that the 32G x 4mm Pen Needle provides equivalent glycemic control compared to the predicate pen needle products, the BD 31G x 5mm and 31G x 8mm Pen Needles. Further, bench testing to ISO Standard 11608-2, was conducted on the 32G x 4mm Pen Needle and met all acceptance criteria as listed in the following Validation /Verification Table. Additionally, the full set of insulin pen families available in the U.S. were tested with the BD 32G x 4mm Pen Needle for compatibility. Connectivity acceptance criteria per ISO 11608-2 were successfully met for all pen families.

Based on comparison of the device features, materials, intended use, bench testing and clinical performance, the BD Pen Needle has shown to be substantially equivalent to the commercially available predicate devices.

The results of these tests demonstrate that the modified BD Pen Needle performs equivalent to the predicate device and is safe and effective when used as intended.

The following table summarizes the validation and verification testing that was performed.

Validation/Verification Tests

Performance Characteristic/ Test description	Test Performed	Results
BDDC-08-011: Comparison of Glycemic Control among Diabetics using the 4mm x 32G BD Pen Needle vs. the 8mm x 31G BD Pen Needle and the 5mm x 31G BD Pen Needle.	Clinical Evaluation comparing subjects' glycemic control, by means of fructosamine levels.	This study demonstrated that the 4 mm x 32G pen needle tested provides equivalent glycemic control and a similar safety profile to two predicate pen needle products – the 5mm x 31G and 8 mm x 31G pen needles. The clinical study summary can be found in Section XV, Clinical Performance.
	Tubing diameters	Per ISO 11608-2, section 4.3.1 (tubing dimensions meet OD and ID requirement).
	Patency of lumen	Per ISO 11608-2, section 4.4 (stylet, having a diameter equivalent to 80% ±2% of lumen ID passes through freely).
	Needle points	Per ISO 11608-2, section 4.5 (visually sharp at 2.5X magnification).
	Needle dislocation (angularity)	Per ISO 11608-2, section 4.8 (4 mm patient end needle length meets needle dislocation requirements).
	Type A needles (length)	Per ISO 11608-2, section 4.3 (patient end within indicated length ± 1.25 mm and cartridge end within 3.5-7.25 mm)
	Cannula load test (No pre-conditioning)	Per ISO 11608-2, section 4.9 (cannula holds force of 22N for 5 seconds).
	Cannula load test (with pre-conditioning)	Per ISO 11608-2, section 4.9 (cannula holds force of 22N for 5 seconds).
	Siliconization (lubrication)	Per ISO 11608-2, section 4.7 (no visible droplets inside/outside surfaces of cannula).
	Universal Fit Compatibility Testing	Per ISO 11608-2, section 4.1 (connectivity (torque). Dose accuracy testing)

The results of these tests demonstrate that the modified BD Pen Needle performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 1 5 2010

Mr. James Haynes
Manager, Regulatory Affairs
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Franklin Lakes, New Jersey 07417-0741

Re: K100005
Trade/Device Name: BD 32G x 4mm Pen Needle
Regulation Number: 21CFR 880.5570
Regulation Name: Hypodermic Single Limen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 5, 2010
Received: February 16, 2010

Dear Mr. Haynes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100005

510(k) Number (if known):

Device Name: BD 32G x 4mm Pen Needle

Indications For Use:

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100005